

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons which follow.

Claims 6, 15, 24, and 33 have been cancelled herein. Claims 1, 11, 20, 29, and 36 have been amended. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, are presented above, with an appropriate defined status identifier.

Claims 1-5, 7-14, 16-23, 25-32, and 34-38 are now pending in this application. Claims 1-5 and 7-9 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over WO 01/10420. Claims 1-38 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO 01/10420 in view of Miranda et al. (U.S. Patent No. 5,656,286). Reconsideration is requested.

Claims 1-5 and 7-9 are Patentable Over WO 01/10420,

Claims 1-5 and 7-9 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by WO 01/10420 (hereinafter "Vickers"). Claim 1 has been amended herein to recite that the composition "comprises no more than about 5 weight % of acid functional monomers." Such a composition is neither disclosed nor suggested by Vickers.

It is well settled that an invention lacks novelty under 35 U.S.C. § 102 *only* if each and every element of the claim is described or disclosed, either explicitly or inherently, in a single prior art reference. *Finnigan Corp. v. International Trade Com'n*, 180 F.3d 1354, 1365 (Fed. Cir. 1999). In fact, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). Here, Vickers does not disclose the instantly claimed invention. Specifically, claims 1-5 and 7-9 are patentable over Vickers as Vickers does not disclose a composition that "comprises no more than about 5 weight % of acid functional monomers."

Claims 1-5 and 7-9, as amended, also would not have been obvious over Vickers. According to the PTO, Vickers "discloses products and uses that contain the same exact

ingredients/components as that of the claimed invention.” It is noted that while Vickers does discuss the administration of methylphenidate, Vickers does not disclose or suggest limiting the amount of acid functional monomers in the composition. As set forth in the instant specification, the applicants discovered that methylphenidate, and in particular the base form, can be unstable and undergoes degradation in the presence of acid functional groups which can reduce the amount of active enantiomer during storage, thus reducing the amount of active methylphenidate available for drug delivery. (See Paragraph [0029]). Vickers does not disclose or suggest that the composition comprise “no more than about 5 weight % of acid functional monomers,” as claimed. Therefore, claim 1 is patentable over Vickers. Moreover, for at least this reason, claims 2-5 and 7-9, which depend from claim 1, are patentable over Vickers.

Claims 1-38 are Patentable Over the Prior Art of Record

Claims 1-38 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Vickers (WO 01/10240) in view of Miranda et al. (U.S. Patent No. 5,656,286). Claims 1, 11, 20 and 29 have been amended herein to recite that the composition and methods “comprises no more than about 5 weight % of acid functional monomers.” Such compositions and methods are neither disclosed nor suggested by Vickers. Moreover, there is nothing in Miranda et al. to overcome the deficiency in Vickers.

Vickers teaches that the adhesive is preferably a block copolymer of the A-B-A structure where one of A and B is an acrylic-type polymeric unit. (pg. 6). Vickers further teaches that block copolymers are preferably acrylic block copolymers. (pg. 7). Vickers also teaches that the polar monomer, such as vinyl acetate, may be present up to 50% w/w of the monomeric mix of the soft segment (a segment having a glass transition temperature below room temperature) of the block copolymer. (pg. 8). Vickers does not disclose or suggest that the composition comprise “no more than about 5 weight % of acid functional monomers,” as set forth in the claims, as amended.

To overcome this deficiency, the Examiner relies on Vickers statement that the “level of residual monomer is below 2000 ppm” (pg. 10). Vickers disclosure regarding the residual

level of monomer indicates what amounts of residual monomer are remaining after the polymerization reaction has proceeded at the appropriate rate. According to the reference, if too much initiator is used, the polymerization will be too rapid causing instant gelling of the mix, and if the level of initiator is too low than the polymerization reaction will not proceed properly. Such a reaction would leave too many monomers unpolymerized and cause the adhesive to lack the structural properties necessary to support the patch. Vickers describes the appropriate level of residual monomer as being below 2000 ppm to insure the appropriate structural integrity of the patch. Vickers does not address the problem that methylphenidate, and in particular the base form, can be unstable and undergo degradation in the presence of acid functional groups which can reduce the amount of active enantiomer during storage, thus reducing the amount of active methylphenidate available for drug delivery.

The person having ordinary skill in the art would not have been motivated by the teachings of Vickers to formulate a composition that "comprises no more than about 5 weight % of acid functional monomers," as set forth in the claims," especially in view of Vickers teachings of acrylic-type polymeric unit being preferred and that polar monomer, such as vinyl acetate, may be present up to 50% w/w of the monomeric mix of the soft segment of the block copolymer.

There is nothing in Miranda et al that overcomes this deficiency in Vickers. Miranda et al. do not disclose or suggest the claimed composition which "includes no more than about 5 weight % of acid functional monomers." In fact, the Examiner does not rely upon Miranda et al. for this suggestion. Moreover, there is no motivation, in the references or elsewhere, to modify any of the references of record to arrive at the instantly claimed invention. Until the present invention, it was not appreciated by the person having ordinary skill in the art the degree of acid functional monomers that may be incorporated into the claimed composition. Neither Vickers, nor Miranda et al., either alone or in combination, disclose or suggest the subject matter of claims 1, 11, 20, and 29. Since the remaining claims depend from these claims, for at least this reason claims 1-38 are patentable over Vickers and Miranda et al.

Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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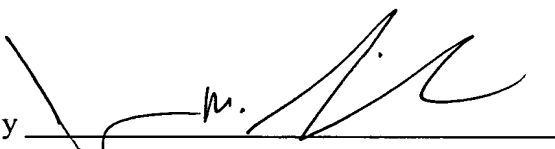
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